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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/623,364	10/23/2000	Alexei Khomutov	933-160P	2717

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EXAMINER
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WHITE, EVERETT NMN

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 06/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/623,364

Applicant(s)

KHOMUTOV ET AL.

Examiner

EVERETT WHITE

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 March 2003.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-8 and 10-16 is/are pending in the application.
- 4a) Of the above claim(s) 8, 10, 11, 15 and 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 12-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other:

Art Unit: 1623

### DETAILED ACTION

1. The amendment filed June 25, 2002 and reply to restriction requirements filed March 20, 2003 have been received, entered and carefully considered. The amendment affects the instant application accordingly:

- (A) Claim 9 has been canceled.
- (B) New Claims 12-16 have been added.
- (C) Claims 1-8, 10 and 11 have been amended.
- (D) Comments regarding Office Action have been provided drawn to
  - (a) 112, 2<sup>nd</sup> paragraph rejection, which has been withdrawn.
  - (b) 102(b) rejection, which has been maintained for the reasons of record.

2. Claims 1-8 and 10-16 are pending in the case.

3. The text of those sections of title 35, U. S. Code not included in this action can be found in a prior Office action.

### ***Answer To Arguments With Traverse***

4. Applicant's election with traverse of Group I, Claims 1-7 and 12-14 in Paper No. 12 is acknowledged. The traversal is on the ground(s) that Groups I and III should be reunited at the very least according to the guidelines promulgated in PCT Administrative Instructions Annex B, Part 2, Examples Concerning Unity of Invention", which Applicants argue that the compound of Group I differs from the compound of Group II by having different substituents on the common structure. Applicants argue that when claims differ in this manner, unity of invention exists where there is a common structure and the different substituents in the Markush group do not change the utility of the claimed compound. Applicants also argue for the rejoining of Group II with Group I on the grounds that when a claim is directed to a compound and another claim is directed to making that claimed compound, unity of invention exists between the two claims. These arguments are not found persuasive because the claims fail to set forth structures of the aminooxy protected derivatives in the Groups and do not clearly show how the aminooxy group is protected. Such broad language in the claims do not support Markush terminology. Furthermore, PCT Rule 13.2 requires that unity of invention exists only when the shared same or corresponding technical feature is a

Art Unit: 1623

contribution over the prior art. Section (f)(i)(B)(1) of Annex B of the Administrative Instructions requires that all alternatives of a Markush Group have a common structure. Although the chemical compounds of Groups I, II and III share a common structure of an aminooxy-cyclodextrin moiety, the compounds are not regarded as being of similar nature because the shared common structure is not seen to be a contribution over the prior art. The "special technical feature" of Group I is an aminooxy protected derivative which is shown by Varaprasad et al (Bioorganic Chemistry, Vol. 14, pages 8-16, 1986) to lack novelty or inventive step. Varaprasad et al discloses a cyclodextrin derivative in the formula disclosed at the top of page 12 wherein the formula at Roman No. II indicates R1 as representing a formula that is within the definition of the broadly claimed aminooxy protected derivative of the instant invention and does not make a contribution over the prior art.

The requirement is still deemed proper and is therefore made FINAL.

***Reply To Final Must Include Cancellation***

5. This application contains claims 8, 10, 11, 15 and 16 drawn to an invention nonelected with traverse in Paper No. 12. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-7 and 12-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In the absence of the specific derivatizations to the chemical core claimed (aminooxy protected derivatives of the aminooxy-cyclodextrin derivatives) or distinct language to describe the structural modifications or the chemical names of the aminooxy protected derivatives of this invention, the identity of said derivatives would be difficult to describe and the metes and bounds of said derivatives that Applicants regard

Art Unit: 1623

as the invention cannot be sufficiently determined because they have not been particularly pointed out or distinctly articulated in the claims. Claim 12 is rejected since the claim is dependent from a rejected independent Claim.

Applicant's arguments the amendment filed June 25, 2002 have been fully considered but they are not persuasive. The amendments set forth in the claims do not overcome the above rejection under 35 U.S.C. 112, 2<sup>nd</sup> paragraph.

***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claim 1 stand rejected under 35 U.S.C. 102(b) as being anticipated by Varaprasad et al (Bioorganic Chemistry, Vol. 14, pages 8-16, (1986)) for the reasons disclosed on page 5 of the Office Action mailed March 27, 2002.

10. Applicant's arguments filed June 25, 2002 have been fully considered but they are not persuasive. Applicants argue against the rejection on the grounds that the Varaprasad et al reference does not contain an amino group protection group, which is removed after it has functioned to protect the amino group in a reaction. However, Applicants argument is base on the intended use of the claimed compound. Applicants are reminded that a difference in intended use cannot render a claimed composition novel. Note *In re Tuominen*, 213 USPQ 89 (CCPA, 1982); *In re Pearson*, 494 F2d 1399; 181 USPQ 641 (CCPA, 1974); and *In re Hack* 114 USPQ 161. Accordingly, the rejection of Claim 1 under 35 U.S.C. 102(b) as being anticipated by Varaprasad et al (Bioorganic Chemistry, Vol. 14, pages 8-16, (1986)) is maintained for the reasons of record.

**Summary**

11. Claims 1-7 and 12-14 are rejected; Claim 8, 10, 11, 15 and 16 are withdrawn from consideration as being directed to non-elected invention.

Art Unit: 1623

**Conclusion**

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

**Examiner's Telephone Number, Fax Number, and Other Information**

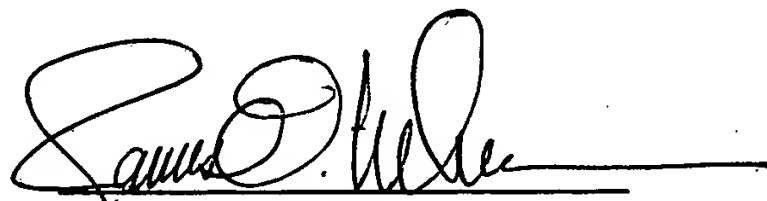
13. For 24 hour access to patent application information 7 days per week, or for filing applications, please visit our website at [www.uspto.gov](http://www.uspto.gov) and click on the button "Patent Electronic Business Center" for more information.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Everett White whose telephone number is (703) 308-4621. The examiner can normally be reached on Monday-Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reached on (703) 308-4624. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

  
E. White

  
James O. Wilson  
Supervisory Primary Examiner  
Technology Center 1600